AMENDED IN ASSEMBLY AUGUST 20, 2001

AMENDED IN ASSEMBLY JULY 19, 2001

SENATE BILL No. 293

Introduced by Senator Torlakson

February 16, 2001

An act to amend Section 4123 of, ~~to add Sections 4011.5 and 4040.7 to,~~ and to add Article 7.5 (commencing with Section 4127) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, *and* making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 293, as amended, Torlakson. Pharmacies: *injectable* sterile drug products.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists and pharmacy corporations in this state. Existing law regulates controlled substances, dangerous drugs, and dangerous devices.

This bill would create new positions within the California State Pharmacy Board in order to carry out the provisions of this act. The bill would appropriate ~~$700,000~~ *$580,000* from the Pharmacy Board Contingent Fund for purposes of the bill.

This bill would authorize the board, based on reasonable belief obtained during an investigation or pharmacy inspection, to issue a cease and desist order to a pharmacy requiring, among other things, the pharmacy to refrain from any activity that posed an immediate threat to the public health or safety. The bill would ~~define ''sterile drug products'' and would~~ implement quality assurance methods regarding the compounding of ~~these substances~~ *injectable sterile drug products.*

The bill would require the board to adopt necessary regulations regarding *injectable* sterile drug products. The bill would require ~~a pharmacy~~ *specified pharmacies* to obtain a license from the board in order to prepare *injectable* sterile drug products. By charging a fee for these licenses which would be deposited into the continuously appropriated Pharmacy Board Contingent Fund, the bill would make an appropriation.

The bill would provide that a violation of this act *or regulations adopted pursuant to this act* would be subject to a fine of up to $2,500. These fines would be deposited into the continuously appropriated Pharmacy Board Contingent Fund and would thereby make an appropriation.

A violation of the Pharmacy Law is a crime. By adding additional requirements to the Pharmacy Law concerning *injectable* sterile drug products, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: $^{2}/_{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature hereby establishes ~~six~~ *five* positions in the California State Board of Pharmacy to implement the provisions of this act. Those positions shall be apportioned as follows: one supervising pharmacy inspector, two pharmacy inspectors, one management services technician, and ~~two~~ *one* office ~~technicians.~~ *technician.*

The sum of ~~seven hundred thousand dollars ($700,000)~~ *five hundred eighty thousand dollars ($580,000)* is hereby appropriated from the Pharmacy Board Contingent Fund to the California State Board of Pharmacy for the costs associated with the implementation of this act, including, but not limited to, the salaries and benefits of the employees described in this section.

SEC. 2. ~~Section 4011.5 is added to the Business and Professions Code, to read:~~

~~4011.5. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that activity in a pharmacy poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from that activity. The cease and desist order may include the immediate closure of all or part of a pharmacy. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.~~

~~(b) Whenever the board orders the closure of a business pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section.~~

~~SEC. 3. Section 4040.7 is added to the Business and Professions Code, to read:~~

~~4040.7. "Sterile drug product" means any dosage form devoid of viable microorganisms or pyrogens, including, but not limited to, parenterals, injectables, and ophthalmics.~~

~~SEC. 4.~~ Section 4123 of the Business and Professions Code is amended to read:

4123. Any pharmacy that contracts to compound a sterile drug product~~, pursuant to a prescription,~~ for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

~~SEC. 5.~~

SEC. 3. Article 7.5 (commencing with Section 4127) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.5. *Injectable* Sterile Drug Products

~~4127. For the purposes of this article, "guidelines" means the "Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products" approved by the American Society for Health-System Pharmacists on April 27, 2000.~~

4127. The board shall adopt regulations establishing standards for compounding sterile drug products in a pharmacy.

4127.1. ~~Sterile drug products shall be compounded in a manner consistent with the guidelines.~~

~~4127.2.~~ (a) A pharmacy shall not compound *injectable* sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. A license shall be required for each location owned or operated by a specific person where *injectable* sterile drug products are compounded. The license shall be renewed annually and is not transferable.

(b) A license to compound *injectable* sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound *injectable* sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound *injectable* sterile drug products may not be issued until the location is inspected by the board and found in compliance with ~~the guidelines and other requirements in this article and in~~ *this article and* regulations adopted by the board.

(c) ~~The applicant for a license to compound sterile drug products shall indicate on the application the risk level or levels, as defined in the guidelines, of drugs to be compounded at that location. The location shall meet the requirements for that risk level indicated in the guidelines. The license issued shall indicate the risk level or levels that may be compounded at that location.~~

~~(d) If a pharmacy wishes to compound sterile drug products that are classified in a risk level, as defined by the guidelines, higher than that indicated on the license, then the licensee shall apply for a change of license from the board at least 30 days prior to commencing the compounding of sterile drug products of a higher risk level. That change of license shall not be granted until the location is inspected by the board and found in compliance with the guidelines for compounding drugs at that risk level.~~

~~(e)~~ A license to compound *injectable* sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with ~~the guidelines and other requirements in this article and in regulations adopted by the~~ *this article and regulations adopted by the* board.

~~4127.3.~~

(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation

of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(e) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.2. (a) A nonresident pharmacy may not compound *injectable* sterile drug products for shipment into the State of California without a license issued by the board pursuant to this section. A license shall be required for each location owned or operated by a specific person or entity where *injectable* sterile drug products are compounded. The license shall be renewed annually.

(b) A license to compound *injectable* sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound *injectable* sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound *injectable* sterile drug products may not be issued *or renewed* until the board receives the following from the nonresident pharmacy:

(1) A copy of ~~the nonresident pharmacy's most recent~~ *an* inspection report *issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.*

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

~~(3) An affidavit, signed by the pharmacist in charge of the nonresident pharmacy, confirming the pharmacy's compliance with the guidelines.~~

~~(c) The applicant for a license to compound sterile drug products shall indicate on the application the risk level or levels, as defined in the guidelines, of drugs to be compounded at that location. The location shall meet the requirements for that risk level indicated in the guidelines. The license issued shall indicate the risk level or levels that may be compounded at that location.~~

~~(d) If the nonresident pharmacy wishes to compound sterile drug products that are classified in a risk level, as defined by the guidelines, higher than that indicated on the license, then the nonresident pharmacy shall apply for a change of license from the~~

~~board at least 30 days prior to commencing the compounding of sterile drug products of a higher risk level. That change of license shall not be granted until the nonresident pharmacy provides the board with copies of the materials required in subdivision (b) updated to reflect the increased risk level.~~

~~4127.4. Pharmacy technicians who participate in the compounding of sterile drug products shall maintain current certification by the Pharmacy Technician Certification Board.~~

~~4127.5. Pharmacies and nonresident pharmacies licensed prior to the effective date of this article who compound sterile drug products shall comply with the terms of this article on or before July 1, 2002.~~

~~4127.6. (a) For each batch of sterile drug product compounded, the pharmacy shall record the following information:~~

~~(1) Identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes.~~

~~(2) Manufacturer lot number and expiration date for each component.~~

~~(3) Component manufacturer or suitable manufacturer identification number.~~

~~(4) Container specifications, including, but not limited to, syringes or pump cassettes.~~

~~(5) Lot or control number assigned to the batch.~~

~~(6) Expiration date of batch-prepared products.~~

~~(7) Date of preparation.~~

~~(8) Identity of personnel involved in preparation. This may be determined by initials, codes, or signatures which divulge the identity of the preparer.~~

~~(b) The pharmacy shall record the lot or control number of sterile drug products provided to patients or prescribers.~~

~~(c) Batch records required by this section shall be retained by the pharmacy for three years.~~

~~4127.7. Each pharmacy issued a license to compound sterile drug products shall maintain written policies and procedures in the pharmacy governing the compounding of sterile drug products. The policies and procedures required by this section shall comply with the board guidelines and include a quality assurance process for compounding sterile drug products.~~

~~4127.8.~~

(c) Pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.

4127.3. (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that activity in a pharmacy requiring a license issued pursuant to Section 4127.1 or 4127.2 poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from that activity. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.

(b) Whenever the board orders the closure of a business pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.

(c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the closure order. Consideration of the owner's contest of the closure order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five days from the date the request of the owner is received by the board. The president shall render a written decision within five days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.

(d) Failure to comply with a closure order issued pursuant to this section shall be unprofessional conduct.

4127.4. Notwithstanding any other provision of law, a violation of this article*, or regulations adopted pursuant thereto,* may subject the person or entity that committed the violation to a

fine of up to two thousand five hundred dollars ($2,500) per occurrence pursuant to a citation issued by the board.

~~4127.9. (a)~~

4127.5. The fee for the issuance of a license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

~~SEC. 6.~~

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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